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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/401,681	09/23/1999	FREDRIC S. YOUNG	17003-23-00U	4988

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EXAMINER

CRAIG, DWIN M

ART UNIT	PAPER NUMBER
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2123

DATE MAILED: 12/29/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/401,681

Applicant(s)

YOUNG, FREDRIC S.

Examiner

Dwin M Craig

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 8-11 is/are rejected.
- 7) ☒ Claim(s) 6 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Claims 1-3 and 5-11 have been presented for reconsideration in view of applicant's amended claim language and Request for Continued Examination under 37 CFR 1.114. Dependent Claim 4 has been cancelled.

Response to Arguments

2. Applicant's arguments filed on 14 October 2003 have been fully considered. Examiners response is as follows:

- 2.1 Regarding Applicant's arguments in regards 35 U.S.C. 103 rejections of Claims 1-11 and the 35 U.S.C. 112 1st and 2nd paragraph rejections of Claim 11:

Applicants have argued that:

The Examiner is thanked for the thorough Office Action. The Examiner has finally rejected all claims. By this amendment, submitted as part of a Request for Continued Examination, claim 4 has been canceled and claims 1, 3, 10, and 11 have been narrowed to more specifically assert the scope and intent of the invention.

The Applicant invites reconsideration in view of amendments and the following arguments.

The Applicant observes that the Examiner has taken the position that the present invention, as originally claimed, is directed to a generalized simulation tool that represents itself as being able to use anything previously invented or that could be invented, though noting that dependent claim 3 is directed to living organisms. The prior art, in various combinations of Carpenter, Thalhammer-Reyero and Keeler, has been cited as representative of generalized simulation systems. By these amendments, it is believed that the claims now fall outside the purview of the prior art.

The Applicant submits that the present invention, particularly as now claimed in claims 1-3, 5-10, is directed to developing minimally complex simulations of living organisms. The present invention is not directed to generalizations of simulations of complex systems. As now claimed, the invention articulates that the nodes of interest are in a nested hierarchy of levels (i.e., where one level is a subset of a next level) representative of a living organism. Inherent in these claims is the concept of employing a minimally complex representation of a living system of interest. The minimally complex representation is the minimum number of nodes that compose a system of interest. These concepts are taught at page 4, lines 15-24 of the present specification. Also included in the claims as amended is the concept of homeostasis in a nested hierarchical structure. This is taught at page 4, lines 7-11. The concept of minimally complex representations of a system is clearly

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taught at page 2 lines 15-17. It is respectfully submitted that all claims now pending contain allowable subject matter.

The Examiner asserts that, in view of Applicant's amended claim language the *Carpenter et al.* reference and the *Keeler et al.* reference are no longer analogous art because, the new claim language is directed to simulations of living organisms and not generalized simulations of complex systems. The Examiner asserts that the Applicants arguments have been persuasive and withdraws the earlier 35 U.S.C. 103 rejections of Claims 1-11, (*see paper number 6.*)

2.2 Regarding the Applicants response to the 35 U.S.C. 112 1st and 2nd paragraph rejections of Claim 11:

Applicants have argued that:

Claim 11 has been rejected as not being supported by the Specification. The Applicant respectfully requests reconsideration. In order to address the concerns of the Examiner, claim 11 has been amended to more closely follow the language employed in the Specification. The concepts of claim 11 are clearly taught by the Specification.

The Examiner asserts that, in light of Applicants amended Claim language, Claim 11 is no longer directed towards subject matter that is not supported in the specification. Specifically, the Examiner asserts that new claim language no longer claims a *hierarchical phase diagram*, for which there was no support in the specification, and instead is now directed towards a *Hierarchical diagram* for which there is support, *see figure 10 in the specification*. The Examiner has found Applicants arguments, in view of the amended claim language, to be persuasive and withdraws the earlier 35 U.S.C. 112 1st paragraph enablement rejection of Claim 11. The Examiner asserts that Claim 11 no longer contains the terms, *object process description*, *scale invariant description*, *phase space and universal module* and thus is no longer indefinite in

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distinctly claiming the subject matter. The Examiner asserts that Applicants arguments are persuasive and withdraws the earlier 35 U.S.C. 112 2nd paragraph rejection of Claim 11.

An updated search has revealed new art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Independent Claims 1, 10 and 11 and dependent Claims 2, 3, 5, 8 and 9 have been rejected under 35 U.S.C. 103(a) as being unpatentable over **Fink et al. U.S. Patent 5,657,255** in view of **McAdams et al. U.S. Patent 5,914,891**.

3.1 Regarding Independent Claims 1, 10 and 11 the *Fink et al.* Reference discloses; a method for simplifying simulation of a complex dynamic system comprising a plurality of interacting nodes of interest, representative of a living organism at a selected plurality of levels of a nested hierarchy of source-sink relationships (**Figure 2 Hierarchy, Figure 1 Item 114 the model, Col. 2 Lines 56-59 and Col. 4 Lines 10-19, modeling biological living systems, Col. 4**

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Lines 58-65 and Col. 10 Lines 37-55, *source-sink relationships*), each node having at least one input, at least one output paired with said at least one input (Figure 5 *Cell Pool, State Change IN, State Change OUT*, Col. 11 Lines 25-43**), and seeking a balanced state as homeostasis at each level in the nested hierarchy (**Col. 6 Lines 42-47 *homeostasis* and Col. 10 Lines 11-16 and Col. 10 Lines 56-65, *balanced state***), each node of interest having at least one transformation of inputs, at least one transformation of outputs (**Figures 4, 5 and 8, Col. 6 Lines 18-34, Col. 8 Lines 7-16**).**

However, the *Fink et al.* reference does not exactly disclose the process of protein generation.

Fink et al. discloses that there is a need in the art for a model that conveys information regarding complex biological systems, *such as production of a protein*, (**Fink et al. Col. 2 Lines 47-49**).

An ordinary artisan would have been motivated to search the simulation of biological system art, in order to overcome the express deficiencies of the reference in regards to modeling the complex process of modeling the production of a protein, in the art of biological system modeling, the *McAdams et al.* reference discloses the modeling of the synthesis of a protein (**Figures 6A and 6B and Col. 14 Lines 34-55, Tables 1-5**).

Thus, it would have been obvious, to one of ordinary skill in the art at the time of the invention, to have modified the hierarchy for modeling complex biological systems with the simulation model of protein production because, intuitive analysis of large genetic regulator networks with positive and negative feedback loops is difficult and the

McAdams et al. reference provides a method to overcome that difficulty (**McAdams et al. Col. 1 Lines 53-61**).

3.2 As regards dependent **Claim 2** the *Fink et al.* reference discloses balance (**Col. 10 Lines 11-16 and Col. 10 Lines 56-65, *balanced state***).

3.3 As regards dependent **Claim 3** the *Fink et al.* reference discloses homeostasis (**Col. 6 Lines 42-47 *homeostasis***).

3.4 As regards dependent **Claim 5** the *Fink et al.* reference discloses multiple inputs and outputs (**Figure 2**).

3.5 As regards to dependent **Claim 8** the *Fink et al.* reference discloses balanced states (**Col. 10 Lines 56-65, *balanced state***).

3.6 As regards to dependent **Claim 9** the *Fink et al.* reference discloses critical points (**Col. 6 Lines 42-47 *homeostasis***).

Allowable Subject Matter

4. Dependent **Claims 6 and 7** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

5. Amended Claims 1-3 and 5-11 have been presented for reconsideration under 37 CFR 1.114, Request for Continued Examination. Dependent Claim 4 has been cancelled. Claims 1-3, 5 and 8-11 are rejected. Claims 6 and 7 are objected to.

5.1 The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

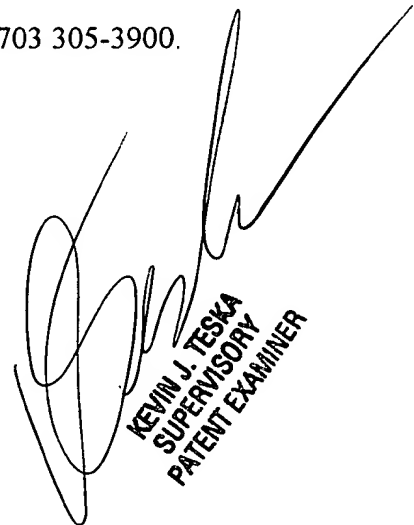
1. *Fink et al.* U.S. Patent 5,808,918 discloses a hierarchical Biological modeling system.
2. *Schaff et al.* U.S. Patent 6,219,440 discloses a method of modeling cellular structures.

5.2 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwain M Craig whose telephone number is 703 305-7150. The examiner can normally be reached on 9:00 - 5:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Teska can be reached on 703 305-9704. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-7239 for regular communications and (703) 746-7238 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-3900.

DMC
December 22, 2003



KEVIN J. TESKA
SUPERVISORY
PATENT EXAMINER